

## REMARKS

Reconsideration of the allowability of the present application in view of the above amendments and the following remarks is requested respectfully.

### Status of the Claims

Claims 1, 3-5, 7-9, 12, 13, 16, 17, 41-43, 47 and 51-63 are pending in this application. Claims 2, 6, 10-11, 14-15, 18-21, and 23-40 are canceled. Claim 3 has been amended.

### Rejection Under 35 USC §101 and §112 first paragraph

Claims 1, 3-5, 7-9, 12, 13, 16-25, 41-43, 47 and 51-63 are rejected under 35 USC §112, first paragraph and 35 USC §101. The Examiner maintains that the claims are not supported by a specific and substantial asserted utility or a well established utility and thus, also are not enabled. In the Office Action spanning pages 3 and 4, the Examiner states that “the specification is completely silent as to using ABCA12 to diagnose lamellar ichthyosis” and rejects the filed affidavit “because the level of skill in the art cannot be relied upon to establish utility for the claimed invention.” The Examiner further states that “[e]ven though ABCA12 is associated with lamellar ichthyosis, Applicants have not explicitly taught that ABCA12 would be useful in the treatment of the disease or that assaying for ABCA12 mutations would be useful for diagnosing lamellar ichthyosis.” Applicants respectfully traverse this rejection with the following remarks.

The instant specification sets forth in the paragraph bridging pages 8 and 9 the mapping of the ABCA12 gene to the 2q34 region of human chromosome 2. Furthermore, the instant specification discloses that this same region is linked with pathologies lamellar ichthyosis, polymorphic congenital cataract and insulin dependent diabetes mellitus. Applicants hypothesize that the ABCA12 gene may be the one causing gene for the phenotype of these pathologies; however that is not the subject matter of Applicants’ claimed invention. Applicants have focused on the lamellar ichthyosis because of their finding of preferential expression of the ABCA12 gene in skin and epithelium, tissues impacted by ichthyosis (page 9, first full paragraph and

Example 3) and the knowledge that the region where ABCA12 is mapped is a region where molecular markers have been found (page 8, lines 4-6).

Applicants' invention relates to diagnostic assays for lamellar ichthyosis by using the statistically linked ABCA gene, splice variants or transcripts therefrom or markers surrounding the ABCA12 locus.

The instant application relates to the discovery of a particular gene that maps to the chromosomal region previously found to be associated with various diseases, including ichthyosis. Because the gene is mapped to the same chromosomal region where those disorders are mapped, Applicants concluded that the gene is a marker for those disorders. The instant application describes polymorphisms of the ABCA12 gene that enables the artisan to identify different forms of the gene. That teaching makes clear there are discernable markers for ABCA12, and those markers can be used for ascertaining the presence of a disorder mapping to that same region or which is found, for example, to be linked to a polymorphism of ABCA12.

The fact that other genetic disorders may be associated with one locus does not diminish the utility as claimed. The establishment of utility can be found directly in the instant specification in the sections cited above. Accordingly, the skilled artisan would decipher the utility of the claimed invention from reading only the instant specification without the need of further research to determine if ABCA12 would be useful in diagnosing ichthyosis.

The Examiner further rejected claims 3-5, 41-43, 47 and 51 for lacking enablement for their full scope stating in the Office Action on page 6 that the claims are overbroad. Applicants respectfully traverse this rejection.

Applicants have amended claim 3 and dependent claims therefrom such that the claimed nucleic acid sequence have the percentage identity to SEQ ID Nos 1-4 in the alternative, and encodes a protein that binds to ATP, contains a transmembrane domain and is an ABCA member.

Clearly, the instant application, and hence the claims, provide a number of specific, substantial and credible uses of the nucleic acids of interest. The specification teaches

thoroughly how to make and how to use a nucleic acid of interest. Therefore, utility exists and a prima facie case of non-enablement has not been made. Accordingly, withdrawal of the § 101 and § 112, first paragraph rejections is requested respectfully.

Rejection under 35 USC §112, first paragraph

Claims 3-5, 41-43, 47 and 51 are rejected under this section for lacking a written description. This rejection is respectfully traversed.

Applicants have amended claim 3 and dependent claims therefrom to recite that the claimed nucleic acids encode a protein that binds to ATP, contains a transmembrane domain and is an ABCA member. As such, it is submitted that this rejection has been overcome and withdrawal of the § 112, first paragraph rejections is requested respectfully.

Rejection under 35 USC §112, first paragraph

Claims 5, 7, 9, 13, 16, 17, 47 and 51-63 are rejected under this section for failing to comply with the written description requirement. This rejection is respectfully traversed.

The specification as filed does provide a written description for the claimed nucleic acids of 8, 9, 19, 27, 28 or 30 nucleotides, nucleic acids of at least 1000 or nucleic acids of at least 1500 nucleotide of any one of SEQ ID NOs:1-4. Support for the claims containing said subject matter may be found, for example, on page 9, lines 23-25, which discloses that the invention relates to a nucleic acid comprising at least 8 consecutive nucleotides of a nucleotide Sequence of any one of SEQ IC NOs: 1-4 or complementary nucleotide sequence thereof, and page 56, Table 3, where specific SEQ ID NOs, contain primers of SEQ ID NO:1 consisting of consecutive nucleotides of lengths 19, 27 and 28.

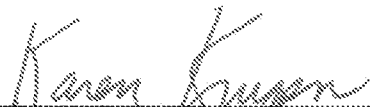
Hence, the written description requirement being satisfied, withdrawal of the rejection is in order.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the rejections, and early indication of allowance are requested

respectfully. Should the Examiner believe that an interview would advance the prosecution of the instant application, Applicants invite her to contact the undersigned at the local exchange noted below.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Karen Krupen", written over a horizontal dotted line.

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